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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,311	02/11/2004	Anthony J. Kinney	BB1538USNA	4023

23906 7590 03/15/2006

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,311	Applicant(s) KINNEY ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 11, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-139 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, 11-12, 16-18 and 26-28, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 312, for example.
- II. Claim 2, 11-12, 16-18 and 26-28, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 5.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 306, for example.
- III. Claim 3, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 10.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 322, for example.
- IV. Claim 4, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 15.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more

carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 320.1, for example.

- V. Claim 5, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 20.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 314, for example.
- VI. Claim 6, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 25.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 298, for example.
- VII. Claim 7, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 30.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 312, for example.
- VIII. Claim 8, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 40.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 306, for example.

- IX. Claim 9, 11-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 50.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 322, for example.
- X. Claim 10-20 and 26-30, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 6.0 % of at least one polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds, and seeds obtained from said plant, classified in class 800, subclass 322, for example.
- XI-XX. Claims 21-25, drawn to oil obtained from the seeds of the plants of claims 1-10, classified in class 426, subclass 601, for example. Groups XI-XX are directed to oil obtained from the seeds of the plants of Groups I-X respectively.
- XXI. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a delta 4 desaturase polypeptide, classified in class 435, subclass 320.1, for example.
- XXII. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a delta 5 desaturase polypeptide, classified in class 435, subclass 320.1, for example.

XXIII. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a delta 6 desaturase polypeptide, classified in class 435, subclass 320.1, for example.

XXIV. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a delta 15 desaturase polypeptide, classified in class 435, subclass 320.1, for example.

XXV. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a delta 17 desaturase polypeptide, classified in class 435, subclass 320.1, for example.

XXVI. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a C18 to C22 elongase polypeptide, classified in class 435, subclass 320.1, for example.

XXVII. Claims 31-32, drawn to a recombinant construct comprising a nucleic acid sequence encoding a C20 to C24 elongase polypeptide, classified in class 435, subclass 320.1, for example.

XXVIII-XXXIV. Claims 33-40, 46-47 and 50-51, drawn to an oilseed plant comprising in its genome the recombinant construct of claim 31 or claim 32, and seeds obtained from said plant, classified in class 800, subclass 306, for example. Groups XXVIII-XXXIV are directed to oilseed plants comprising the recombinant constructs of Groups XXI-XXVII respectively.

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XXXV-XLI. Claims 41-44, 48 and 52, drawn to oil obtained from the seeds of claims 37-40, classified in class 426, subclass 601, for example. Groups XXXV-XLI are directed to oil obtained from the seeds of Groups XXVIII-XXXIV respectively.

XLII-XLVIII. Claim 45 and 49, drawn to a method comprising transforming a plant with the construct of claim 32, classified in class 800, subclass 281, for example. Groups XLII-XLVIII are directed to methods comprising transforming a plant with the constructs of Groups XXI-XXVII respectively.

XLIX-LV. Claim 53, 60, 103, 110 and 122, drawn to a food product or food analog which has incorporated the oil of claim 21, classified in class 426, subclass 635, for example. Groups XLIX-LV are directed to food product or food analogs which have incorporated the oil of Groups XI-XX respectively.

LVI-LXII. Claims 54-59, 61-66, 104-109, 111-116 and 123-128, drawn to a food product or food analog which has incorporated the oil of claims 41-44, 48 or 52, classified in class 426, subclass 635, for example. Groups LVI-LXII are directed to food product or food analogs which have incorporated the oil of Groups XXXV-XLI respectively.

LXIII-LXXII. Claim 67, drawn to a beverage which has incorporated the oil of claim 21, classified in class 426, subclass 590, for example. Groups LXIII-LXXII are directed to food product or food analogs which have incorporated the oil of Groups XI-XX respectively.

LXXIII-LXXIX. Claims 68-73, drawn to a beverage which has incorporated the oil of claims 41-44, 48 or 52, classified in class 426, subclass 590, for example.

Groups LXXIII-LXXIX are directed to food product or food analogs which have incorporated the oil of Groups XXXV-XLI respectively.

LXXX-LXXXIX. Claim 74, drawn to an infant formula which has incorporated the oil of claim 21, classified in class 426, subclass 585, for example. Groups LXXX-LXXXIX are directed to food product or food analogs which have incorporated the oil of Groups XI-XX respectively.

XC-XCVI. Claims 75-80, drawn to an infant formula which has incorporated the oil of claims 41-44, 48 or 52, classified in class 426, subclass 585, for example. Groups XC-XCVI are directed to food product or food analogs which have incorporated the oil of Groups XXXV-XLI respectively.

XCVII-CVI. Claim 81, drawn to a nutritional supplement which has incorporated the oil of claim 21, classified in class 426, subclass 648, for example. Groups XCVII-CVI are directed to food product or food analogs which have incorporated the oil of Groups XI-XX respectively.

CVII-CXIII. Claims 82-87, drawn to a nutritional supplement which has incorporated the oil of claims 41-44, 48 or 52, classified in class 426, subclass 648, for example. Groups CVII-CXIII are directed to food product or food analogs which have incorporated the oil of Groups XXXV-XLI respectively.

CXIV-CXXIII. Claim 88, 93, 98 and 129, drawn to a food product or food analog which has incorporated the seed of claim 13 or claim 16, classified in class 426, subclass 630, for example. Groups CXIV-CXXIII are directed to food product or food analogs which have incorporated the seed of Groups I-X respectively.

CXXIV-CXXX. Claims 89-92, 94-97, 99-102 and 130-133, drawn to a food product or food analog which has incorporated the seed of claims 37-40, classified in class 426, subclass 630, for example. Groups CXXIV-CXXX are directed to food product or food analogs which have incorporated the seed of Groups XXVIII-XXXIV respectively.

CXXXI-CXL. Claim 117, drawn to a whole bean soy product made from the seed of claim 16, classified in class 426, subclass 629, for example. Groups CXXXI-CXL are directed to whole bean soy product made from the seed of Groups I-X respectively.

CXLI-CXLVII. Claims 118-121 drawn to a whole bean soy product made from the seed of claims 37-40, classified in class 426, subclass 629, for example. Groups CXLI-CXLVII are directed to whole bean soy product made from the seed of Groups XXVIII-XXXIV respectively.

CXLVIII. Claims 134 and 138, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises polyunsaturated fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein the ratio of EPA:DHA is in the range from 1:100 to 860:100, and seed obtained from said plant, classified in class 800, subclass 312, for example.

CXLIX. Claims 135 and 138, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises polyunsaturated fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein the ratio of EPA:DHA is in the range from 1:100 to 860:100 and further

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wherein the total seed fatty acid profile further comprises less than 2.0% arachidonic acid, and seed obtained from said plant, classified in class 800, subclass 306, for example.

- CL. Claims 136 and 138, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises polyunsaturated fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein the ratio of DHA:EPA is in the range from 1:100 to 110:100, and seed obtained from said plant, classified in class 800, subclass 322, for example.
- CLI. Claims 137-138, drawn to an oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises polyunsaturated fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein the ratio of DHA:EPA is in the range from 1:100 to 110:100 and further wherein the total seed fatty acid profile further comprises less than 2.0% arachidonic acid, and seed obtained from said plant, classified in class 800, subclass 320.1, for example.
- CLII-CLV. Claim 139, drawn to oil obtained from the seeds of the plants of any of Claims 134-137. Groups CLII-CLV are directed to oil obtained from the seeds of the plants of Groups CXLVIII-CLI respectively, classified in class 426, subclass 601, for example.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-X, XXVIII-XXXIV and CXLVIII-CLI are distinct inventions. The plants and seed of inventions I-X, XXVIII-XXXIV and CXLVIII-CLI differ from one another in their total seed fatty acid profile and in the type of recombinant construct, if any, that they comprise.

Inventions X-XX, XXV-XLI and CLII-CLV are distinct inventions. The oils of inventions X-XX, XXV-XLI and CLII-CLV differ from one another in source and composition.

Inventions XXI-XXVII are distinct inventions. The constructs of inventions XXI-XXVII differ from one another in primary sequence, nature of components and their arrangement, and in the function and/or mechanics of operation.

Inventions XLIX-LXII and CXIV-CXXX are distinct inventions. The foods of inventions XLIX-LXII and CXIV-CXXX differ from one another in source and composition.

Inventions LXIII-LXXIX are distinct inventions. The beverages of inventions LXIII-LXXIX differ from one another in source and composition.

Inventions LXXX-XCVI are distinct inventions. The infant formulas of inventions LXXX-XCVI differ from one another in source and composition.

Inventions XCVII-CXIII are distinct inventions. The nutritional supplements of inventions XCVII-CXIII differ from one another in source and composition.

Inventions CXXXI-CXLVII are distinct inventions. The whole bean soy products of inventions CXXXI-CXLVII differ from one another in source and composition.

Inventions I-X, XXVIII-XXXIV, CXLVIII-CLI, X-XX, XXV-XLI, CLII-CLV, XXI-XXVII, XLIX-LXII, CXIV-CXXX, LXIII-LXXIX, LXXX-XCVI, XCVII-CXIII and CXXXI-CXLVII are distinct inventions. The plants, oils, constructs, foods, beverages, infant formulas, nutritional supplements and whole bean soy products of inventions I-X, XXVIII-XXXIV,

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CXLVIII-CLI, X-XX, XXV-XLI, CLII-CLV, XXI-XXVII, XLIX-LXII, CXIV-CXXX, LXIII-LXXIX, LXXX-XCVI, XCVII-CXIII and CXXXI-CXLVII differ from each another in composition, source, function, use and classification.

Inventions XLII-XLVIII and inventions I-X, CXLVIII-CLI, X-XX, XXV-XLI, CLII-CLV, XLIX-LXII, CXIV-CXXX, LXIII-LXXIX, LXXX-XCVI, XCVII-CXIII and CXXXI-CXLVII are distinct inventions. The methods of inventions XLII-XLVIII do not require the use of or result in the production of the products of inventions I-X, CXLVIII-CLI, X-XX, XXV-XLI, CLII-CLV, XLIX-LXII, CXIV-CXXX, LXIII-LXXIX, LXXX-XCVI, XCVII-CXIII and CXXXI-CXLVII.

Inventions XLII-XLVIII are distinct inventions. The methods of inventions XLII-XLVIII utilize different materials and result in the production of different products.

Inventions XLII-XLVIII and inventions XXVIII-XXXIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic plant can be made by another and materially different process, such as by cellular transformation followed by regeneration, regeneration of cells obtained from transgenic plants, or by breeding of transgenic plants.

Inventions XXI-XXVII and inventions XLII-XLVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

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using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as a hybridization method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their recognized divergent subject matter, and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

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See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC



3/10/06